

TO: INTERESTED PARTIES

SUBJECT: HIV REPORTING REGULATIONS AND HIV-RELATED RESEARCH

This letter is to inform you how the current HIV reporting regulations apply to HIV antibody and viral load test results that are generated by research studies. As you are aware, a non-name system of HIV reporting took effect in California on July 1, 2002, (California Code of Regulations, Title 17, Sections 2641.5-2643.20, which can be accessed at <http://www.dhs.ca.gov/AIDS>). Since then, the Office of AIDS (OA) has received several requests by researchers to clarify how these regulations apply to specific HIV-related research studies conducted in the State.

The current HIV reporting regulations do not specifically address HIV antibody and viral load test results obtained from all types of research studies. To remedy this situation, we hope to amend the regulations to clarify how HIV reporting applies to all research results. Until that time, however, the principal investigator(s) of a research project of a type either addressed or not addressed by the current HIV reporting regulations may apply to OA for exemption from the regulations.

EXEMPTION TO THE CURRENT HIV REPORTING REGULATIONS

For purposes of determining current exemption status, research projects that generate HIV antibody and/or viral load test results are divided into two categories:

- I. Research projects starting before July 1, 2002.
- II. Research projects starting on or after July 1, 2002.



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I. Research Projects Starting Before July 1, 2002

All HIV antibody and viral load test results of a research project that started prior to July 1, 2002, are exempt from the current HIV reporting regulations. This exemption extends to all results generated after July 1, 2002, if the results are generated as part of the initial research project. This letter may be used as written proof of exemption to the current HIV reporting regulations for such projects, as long as:

- a) The principal investigator(s) of the research project can provide proof that the research project began prior to July 1, 2002; and
- b) The principal investigator(s) of an active research project can provide proof that the protocol of the research project has current approval status from an Institutional Review Board, Ethics Committee, or Human Subjects Committee.

Failure to meet either a) or b) will result in immediate termination of exemption status, and the principal investigator(s) will be viewed by the Department of Health Services as being in violation of the California HIV reporting regulations.

II. Research Projects Starting After July 1, 2002

HIV antibody and viral load test results from a research project that started after July 1, 2002, are not exempt from the current HIV reporting regulations except under specific conditions stated in the regulations. However, the principal investigator(s) of a research project may apply to OA to have these results exempted from the HIV reporting regulations. OA will review all submitted exemption requests for research projects on an individual basis. In order to apply for an exemption, the principal investigator(s) of the research study must submit the following to OA via Certified Mail:

- a) A cover letter requesting an exemption to the current HIV reporting regulations for all HIV antibody and viral load test results generated as part of the specifically named research project. This letter must have the original signature of the principal investigator(s), should explain why such an exemption is necessary for successful completion of the research project, and should detail how HIV antibody and/or viral load test results are handled as part of the specifically named research project;

- b) A copy of the letter sent to the principal investigator by an Institutional Review Board, Ethics Committee, or Human Subjects Committee that approves the current protocol of the specifically named research project or renews/extends a previous approval. This letter can be dated no earlier than one year prior to the date the letter is received by OA, and must have current contact information for at least one person representing the approving Institutional Review Board, Ethics Committee, or Human Subjects Committee; and
- c) A copy of the current study protocol and Informed Consent Form.

These documents should be sent to Juan Ruiz, M.D., Dr.P.H., Acting Chief, HIV/AIDS Epidemiology Branch, OA at the address provided at the end of this letter. The documents will be reviewed by OA, and upon determination, OA will notify the principal investigator(s) of the decision in writing. If OA agrees to exempt a project, the exemption applies only to that specific project. If OA denies the exemption request, an explanation will be provided in writing. Exemption requests lacking any of the required documentation will be returned without review.

The written notification of whether or not exemption status is granted will be sent to the principal investigator(s) within 60 calendar days of receipt of the complete exemption request. If this notification is not received within the 60 days, the principal investigator(s) should contact Dr. Juan Ruiz. The principal investigator(s) may appeal the decision set forth by OA, but may do so only in writing to Dr. Juan Ruiz.

NONCOMPLIANCE WITH THE CURRENT HIV REPORTING REGULATIONS

Principal investigators of research projects that generate HIV antibody or viral load test results will be viewed by the Department of Health Services as not complying with the current HIV reporting regulations of California if these results are not reported to the State as set forth in the regulations and if any of the following are true:

- a) The research project began before July 1, 2002, but either a) or b) as stated in Section I is not true; or
- b) The research project began after July 1, 2002, but the principal investigator(s) does not apply to OA for an exemption to the HIV reporting regulations. (OA recommends that the principal investigator(s) of such research projects that are underway upon receipt of this letter halt HIV antibody and viral load testing and apply for an exemption immediately); or

- c) The research project began after July 1, 2002, the principal investigator(s) applies to OA for an exemption and is denied an exemption, and the principal investigator(s) begins or continues the research project, even if the decision set forth by OA is under appeal.

AMENDING THE CURRENT CALIFORNIA HIV REPORTING REGULATIONS

OA intends to amend the current HIV reporting regulations to clarify how HIV reporting applies to HIV antibody and viral load test results generated as part of research studies conducted in California. The time frame to complete this process cannot be predicted. During the amendment process, OA welcomes the input from researchers and others who conduct HIV antibody and/or viral load testing in California. If you are interested in making recommendations for the proposed amendment, please contact Dr. Juan Ruiz at (916) 449-5832 or Jim Creeger, Chief, HIV/AIDS Case Registry Section, OA, at (916) 449-5866.

HIV reporting exemption requests for research projects may be sent by Certified Mail to:

Juan Ruiz, M.D., Dr.P.H.
Acting Chief
HIV/AIDS Epidemiology Branch
Office of AIDS
Department of Health Services
1616 Capital Avenue, Suite 616
Sacramento, CA 95814

I encourage you to share this letter regarding HIV-related research and HIV reporting with other interested colleagues.

Sincerely,

original signed by Michael Montgomery

Michael Montgomery, Chief
Office of AIDS

cc: See Next Page

Interested Parties
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cc: Juan Ruiz, M.D., Dr.P.H.
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